



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,612	05/14/2001	Thomas Spies	FHCC:003USC1	9260

7590

09/09/2003

Steven L. Highlander, Esq.  
FULBRIGHT & JAWORSKI L.L.P.  
Suite 2400  
600 Congress Avenue  
Austin, TX 78701

EXAMINER

VANDERVEGT, FRANCOIS P

ART UNIT PAPER NUMBER

1644

DATE MAILED: 09/09/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/855,612

Applicant(s)

SPIES ET AL.

Examiner

F. Pierre VanderVegt

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

Art Unit: 1644

### **DETAILED ACTION**

The Examiner in charge of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to F. Pierre VanderVegt, Ph.D. in Art Unit 1644.

This application is a continuation of U.S. Application Serial Number 09/303,161, which claims the benefit of the filing date of provisional application 60/029,044.

Claims 26-101 have been canceled.

Claims 1-25 are currently pending and are the subject of examination in the present Office Action.

**In view of Applicant's response filed June 16, 2003, all previous grounds of rejection are withdrawn.**

**The following represent new grounds of rejection and this Office Action is made Non-Final.**

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Briefly, claims 1-25 are drawn to a method of detecting a cancer cell in a sample comprising detecting a cancer cell in a sample. Said method encompasses MICA or MICB binding agents, wherein said binding agent is an antibody that can be labeled or can be bound by a second antibody, which in turn can be labeled. Said method also encompasses amplifying a MICA or MICB transcript.

The specification discloses on page 9 that the "inventors have shown that MICA is expressed in various cancer cell lines suggesting that cells may be screened for the overexpression of MICA and/or MICB, its presence indicating potential carcinogenesis." The specification further discloses that the

Art Unit: 1644

“expression of MICA in tumor cells provides a marker for diagnostic screening methods for cancer in, for example, tumor or tissue biopsy samples” (page 10, lines 4-5), and that “MICA and/or MICB expression in tumor cells may be detected” (page 10, lines 5-6). The specification also discloses on page 75, lines 1-9 that MICA was detected on tumor cell lines HT29 (colon carcinoma) and U373 (astrocytoma).

However, the specification does not disclose how to correlate the level of MICA/B expression in a sample to the presence of cancer versus the level of MICA/B expression in normal tissue or due to other factors. Groh et al (PNAS 93:12445-12450; of record) teaches that MICA and MICB are normally expressed in the gastrointestinal epithelium but does not indicate expression associated with cancer cells (see entire article, Abstract in particular). Groh et al (Science 1998 279:1737-1740; U on form PTO-892) discloses expression of MICA and MICB is stress related and may be indicative of damaged, infected or transformed intestinal epithelial cells (see entire report, page 1740 in particular).

Given that the state of the art at the time the invention was made does not appear to teach the expression of MICA or MICB solely in association with cancer cells, the artisan would not have been able to predict that the mere detection of MICA and/or MICB in a sample would be indicative of cancer as opposed to being present normally or due to some other form of stress on the originating tissue or organism of the sample. The instant disclosure provides limited guidance in the specification regarding a method for the artisan to detect a cancer cell in a sample comprising identifying expression of MICA or MICB in said sample without correlation of that expression level to the expression level in normal tissue or samples which may exhibit stress induced expression of MICA and/or MICB.

Given the limited working examples in the specification, the state of the art at the time the invention was made and the level of guidance required to practice the claimed invention, it would require undue experimentation for one of skill to predict which if any types of cancer cells could be detected in a sample comprising identifying expression of MICA or MICB in said sample, without further guidance from the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-25 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are:

Correlation of the level of MICA or MICB expression in the sample to the presence of cancer.

Art Unit: 1644

The claims are drawn to a diagnostic method in which the level of MICA and/or MICB expression is used to detect a cancer cell in a sample. However, MICA and MICB are MHC-related stress proteins that are also expressed under conditions of stress other than cancer, as well as on normal intestinal epithelial cells. Accordingly, in order to make a determination of cancer, the level of expression in a sample must be contrasted to expression under normal or stress conditions.


*Conclusion*

4. No claim is allowed.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (703) 305-4441. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

F. Pierre VanderVegt, Ph.D.  
Patent Examiner  
September 8, 2003

  
CHRISTINA CHAN  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600